

Message

From: Strauss, Linda [Strauss.Linda@epa.gov]
Sent: 10/2/2017 9:14:17 PM
To: Beck, Nancy [Beck.Nancy@epa.gov]; Wise, Louise [Wise.Louise@epa.gov]
Subject: FW: Genetically Engineered Mosquitos regulatory responsibility from FDA to EPA -- announcement expected this week
Attachments: CVMU_Final_GFI_236_Mosquito_OCC cleared.docx

Checking with others too.

From: Strauss, Linda
Sent: Monday, October 02, 2017 5:14 PM
To: Grantham, Nancy <Grantham.Nancy@epa.gov>
Subject: RE: Genetically Engineered Mosquitos regulatory responsibility from FDA to EPA -- announcement expected this week

Here's what I think.

1. It would have to be a joint press release with FDA since they have the lead with the document. It would be FDA and EPA are announcing that approval is being transferred from FDA to EPA.
2. The public and stakeholders don't care what Agency has the lead – it's all government. So obviously we would have to say how what we're doing will make something better and FDA would have to agree to it:

Ex. 5 - Deliberative Process

Hmm, I like it if FDA would agree to it! Do you want to reach out to Anne Norris, or want me to tonight or tomorrow?

Attached is the listserv that FDA was planning to send and that we would also send on WEDNESDAY.

Linda

From: Grantham, Nancy
Sent: Monday, October 02, 2017 4:24 PM
To: Strauss, Linda <Strauss.Linda@epa.gov>
Subject: FW: Genetically Engineered Mosquitos regulatory responsibility from FDA to EPA -- announcement expected this week

See below – will you check with others in ocspp re: press release ?

Thanks ng

Nancy Grantham
Office of Public Affairs

US Environmental Protection Agency
202-564-6879 (desk)
202-253-7056 (mobile)

From: Graham, Amy
Sent: Monday, October 02, 2017 4:18 PM
To: Grantham, Nancy <Grantham.Nancy@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Ferguson, Lincoln <ferguson.lincoln@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>; Konkus, John <konkus.john@epa.gov>
Subject: RE: Genetically Engineered Mosquitos regulatory responsibility from FDA to EPA -- announcement expected this week

This is a big deal – are we amplifying with a press release? I don't think we want a listerv being the first announcement of this do we?

From: Grantham, Nancy
Sent: Monday, October 2, 2017 4:01 PM
To: Bowman, Liz <Bowman.Liz@epa.gov>; Graham, Amy <graham.amy@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Ferguson, Lincoln <ferguson.lincoln@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>; Konkus, John <konkus.john@epa.gov>
Cc: Grantham, Nancy <Grantham.Nancy@epa.gov>
Subject: Genetically Engineered Mosquitos regulatory responsibility from FDA to EPA -- announcement expected this week

FYI – on this regulatory responsibility transferring from FDA to EPA – as genetically engineered mosquitos are considered pesticides.

Nancy Beck is looped in on this. FDA will issue a listserv which we will amplify (attached)

See background and Q and A below.

Thanks ng

Background for EPA Internal Use

Ex. 5 - Deliberative Process

For the past several years, the Oxitec mosquito has been under FDA regulatory purview as a “new animal drug” under the Federal Food, Drug, and Cosmetic Act and has yet to be approved for general use. With this transfer of responsibility to EPA, the Oxitec mosquito will now be regulated as a pesticide.

Back-Pocket Qs and As

Why would EPA now regulate a GE mosquito used for population control?

Ex. 5 - Deliberative Process

Why is the question of which agency will regulate GE mosquitoes being addressed at this time as part of the Coordinated Framework Update effort? Why not when companies first indicated they were developing GE mosquitoes?

Ex. 5 - Deliberative Process

How does EPA regulate pesticides?

Ex. 5 - Deliberative Process

Does USDA play a role in the regulation of insects?

Ex. 5 - Deliberative Process

How do *Wolbachia* mosquitoes currently being regulated by EPA for population control differ from the GE mosquito?

Ex. 5 - Deliberative Process

How did it happen that one product intended to lower the number of mosquitoes in the environment is currently being reviewed by EPA as a pesticide, while another mosquito product that is also intended to lower the mosquito population, up until this action, has been reviewed by FDA?

Ex. 5 - Deliberative Process

Why do we need these mosquito products when chemical pesticides can be used to kill mosquitoes?

Ex. 5 - Deliberative Process

If the GE mosquito had gone to EPA first, would it already have a final determination?

Ex. 5 - Deliberative Process

How does this realignment of regulatory responsibility affect the potential use of these mosquitoes in countering the Zika outbreak in the United States?

Ex. 5 - Deliberative Process

What does this mean for the developer of a GE mosquito, Oxitec, whose product is currently under review at FDA? Does this mean that Oxitec will have to go through additional review at EPA?

Ex. 5 - Deliberative Process

Nancy Grantham
Office of Public Affairs
US Environmental Protection Agency
202-564-6879 (desk)

202-253-7056 (mobile)

From: Strauss, Linda
Sent: Friday, September 29, 2017 12:48 PM
To: Grantham, Nancy <Grantham.Nancy@epa.gov>
Subject: FW: GE Mosquito Final Guidance Announcement

The exact timing of the FDA announcement next week is "still being determined." Attached is their listserv and Q/A's.

From: Strauss, Linda
Sent: Friday, September 29, 2017 12:46 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Sisco, Debby <Sisco.Debby@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Lantz, Tracy <Lantz.Tracy@epa.gov>; Perlis, Robert <Perlis.Robert@epa.gov>; Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Subject: FW: GE Mosquito Final Guidance Announcement

Hello, here's FDA's listerv and Q's and A's.

The listserv has rec'd final FDA/legal approval. Let me know if we have any critical show-stoppers. It looks good to me, but you are the experts. Obviously, we'll want to use the same listserv as FDA. Let me know if we have any critical issues w/their Q's and A's as well.

Where are the EPA Q's and A's in the review chain? Will those be coming to me today? FDA would like to see those.

Thanks for all your work and expertise!

Linda

From: Norris, Anne [<mailto:Anne.Norris@fda.hhs.gov>]
Sent: Friday, September 29, 2017 12:23 PM
To: Strauss, Linda <Strauss.Linda@epa.gov>; StClair, Christie <StClair.Christie@epa.gov>; Valentine, Julia <Valentine.Julia@epa.gov>; Daguillard, Robert <Daguillard.Robert@epa.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Cc: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Flamm, Eric <Eric.Flamm@fda.hhs.gov>; Epstein, Laura <Laura.Epstein@fda.hhs.gov>; McNally, Robert <McNally.Robert@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

Hi EPA,

Attached are our CVM Update and Responsive QAs for the GE mosquito final guidance for your awareness. They have received legal clearance from our Office of the Chief Counsel. The responsive QAs in red are new additions to our list of questions since we shared with you in January for the draft guidance, but many of the questions you saw in January now have modified responses to reflect current circumstances.

The exact timing of the announcement is still being determined and we will keep you posted. When you have developed your listserv and QAs, could you please share with us for awareness?

Please let us know if you have any questions or concerns.

Thanks!
Anne

From: Norris, Anne
Sent: Thursday, September 28, 2017 2:13 PM
To: 'Strauss, Linda'; 'StClair, Christie'; 'Valentine, Julia'; 'Daguillard, Robert'; Putnam, Juli
Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura; 'Mcnally.Robert@epa.gov'; 'Milewski, Elizabeth'; 'Mendelsohn, Mike'
Subject: RE: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

Good afternoon,

We just received confirmation that this announcement will not be happening until early next week. We're awaiting precise timing, but wanted to let you know that the guidance is not going out tomorrow as originally anticipated.

Will be in touch when we know more, but hope to have the CVM Update to you very soon and the responsive QAs should follow shortly after that.

Thanks,
Anne

From: Norris, Anne
Sent: Wednesday, September 27, 2017 5:46 PM
To: 'Strauss, Linda'; 'StClair, Christie'; 'Valentine, Julia'; 'Daguillard, Robert'; Putnam, Juli
Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura; 'Mcnally.Robert@epa.gov'; 'Milewski, Elizabeth'; 'Mendelsohn, Mike'
Subject: RE: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

To recap status for everyone: Linda will be in the office Thursday and Friday and she's steering the ship for EPA communications. The EPA team is working on responses to anticipated questions from press and stakeholders. FDA will share our comms tomorrow as soon as we are able.

If you have any questions or concerns, please let us know.

Thanks,
Anne

From: Norris, Anne
Sent: Wednesday, September 27, 2017 5:02 PM
To: 'Strauss, Linda'; 'StClair, Christie'; 'Valentine, Julia'; 'Daguillard, Robert'; Putnam, Juli
Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura; 'Mcnally.Robert@epa.gov'; Milewski, Elizabeth; Mendelsohn, Mike
Subject: RE: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

Looping in Bob, Elizabeth, and Mike now because I tried calling all four of the EPA communications contacts we have on this issue and can't reach anyone. Normally, I'd wait until the morning and try again, but given the time constraints, we just need to ensure that someone from EPA communications is handling this. Linda's voicemail said she's out of the office on Thursday and Friday, so hoping that if she's already signed off and taking leave, that you may be able to suggest who else we can contact.

Thanks,
Anne

From: Norris, Anne
Sent: Wednesday, September 27, 2017 4:42 PM
To: Strauss, Linda; StClair, Christie; Valentine, Julia; 'Daguillard, Robert'; Putnam, Juli
Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura

Subject: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK
Importance: High

Hi Linda,

We just learned that this final guidance is on an EXTREMELY fast trajectory and we're almost certainly going to be announcing by this Friday (9/29). Unfortunately, our communications documents are still in clearance and it would be premature to send them to you in case edits still need to be made. At this point, we should be able to share tomorrow, but it's unclear at what time.

We will share our CVM Update and Responsive QAs at the earliest point possible; however, if you wait until after you view our comms to start developing your QAs or talking points, you won't be allowing yourselves adequate time. Additionally, our responsive QAs are primarily geared toward addressing the questions that the FDA anticipates getting, which won't be very helpful for EPA's needs when it comes to questions that will be directed to EPA from media and stakeholders. Of particular sensitivity right now is the issue of mosquitoes and hurricane relief.

Given the short timeframe, we would strongly suggest that you and your team consult with the EPA policy team working on this issue to get their thoughts on what issues/questions they expect to arise and how they would advise you to handle them. My understanding is that those people are Bob McNally, Elizabeth Milewski, and Mike Mendelsohn.

As Juli had previously mentioned, some examples of the types of questions you might get could be things like:

- What further regulation will the sponsor have to go through to conduct field trials in jurisdictions within the US or to get a commercial approval for the mosquitoes? Will EPA rely on the data the sponsor already provided to the FDA? How long will the process take?
- Do you have any applications/permits/whatever the correct terminology is from Oxitec in house that you are currently reviewing?
- Does the EPA have comment on FDA's guidance? Will this delay the approval/permitting of Oxitec's GE mosquitoes to Hurricane-stricken areas?

Please keep in touch with questions and concerns – feel free to call me anytime at 240-402-0132. We'll reach out tomorrow about the status of our communications and to set up a call with you, if needed.

Thanks,
Anne

Anne Norris
Health Communications Specialist

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